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November 20, 1998

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Kimberly Popper Center for Drug Evaluation & Research (HFD21) **FDA** 5600 Fisher's Lane Rockville, MD 20857

Re: Rev. John H. R. Ellis, D. Min., Priest-in-Charge St. Bernard Catholic Church P. O. Box 1036 Holmes Beach, Florida 34218-1036

Dear Ms. Popper:

As a respected physician of Manatee County, Florida, I am providing this letter in support of Reverend Ellis who has requested your help in getting 4-Aminopyridine on the list of approved drugs before November 21, 1998, as per the Pharmacy Modernization Act, passed November 21, 1997.

He is a priest in the Diocese of Venice who has Multiple Sclerosis. This is the only medication known to help his form of MS. It has put it from the progressive state into remission. Furthermore, there are several thousand people depending on this medication in the U. S. as well. While it is not a cure, it's highly effective in putting his type of MS into remission. I understand this treatment is prescribed by Dr. Victor Rivera, Professor, Department of Neurology at Baylor College of Medicine, International Multiple Sclerosis Center. It is compounded by the Compounding Shop in Houston, Texas.

Reverend Ellis has been on this medication since January 1994 and is functioning very well. As a matter of fact, very few people in his parish even realize that he has MS. However, without 4-Aminopyridine his condition would rapidly deteriorate and functioning as a priest would soon become physically impossible. Therefore, it is being requested for your assistance to put 4-Aminopyridine on the Federal list of approved drugs before November 21, 1998. This medication is critical for keeping this type of MS in remission.

Thank you greatly for your assistance in helping Father Ellis and those other unfortunate patients afflicted with this condition.

Sincerely.

Robert J. Subbiondo, M.D., FACC

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